K131275

SIEMENS

510(k) Summary

NOV 08 2013

510(k) Submission Information:

Device Manufacturer:	Siemens Healthcare Diagnostics
Contact name:	Elisabeth Warriner, Regulatory Technical Specialist
Phone:	916-374-3244
Fax:	916-372-6418
Date prepared:	August 27, 2013
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram-Positive MIC/Combo Panels with Tigecycline (0.12-8 mcg/ml)
Intended Use:	To determine antimicrobial agent susceptibility
Classification:	Class II
Product Code:	LTT
510(k) Notification:	New antimicrobial - Tigecycline
Predicate device:	MicroScan Dried Gram-Positive MIC/Combo Panels – Linezolid (K003619)

510(k) Summary:

MicroScan Dried Gram-Positive MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-positive bacteria.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in broth and dehydrated. Various antimicrobial agents are diluted in broth to concentrations bridging the range of clinical interest. Panels are rehydrated with water after inoculation with a standardized suspension of the organism. After incubation in a non-CO_2 incubator for 16-20 hours, the minimum inhibitory concentration (MIC) for the test organism is read by determining the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan Dried Gram-Positive MIC/Combo Panel with Tigecycline demonstrated substantially equivalent performance when compared with an CLSI frozen Reference Panel, as defined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", dated August 28, 2009. The Premarket Notification (510[k]) presents data in support of the MicroScan Dried Gram-Positive MIC/Combo Panel with Tigecycline. MicroScan Dried Gram-Positive Tigecycline is a qualitative test.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Gram-Positive Panel by comparing its performance with a CLSI frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The Dried Gram-Positive Panel demonstrated acceptable performance with an overall Categorical Agreement of 99.4% for Tigecycline when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with Tigecycline, regardless of which inoculum method (i.e., Turbidity and Prompt™), or instrument (autoSCAN®-4 and WalkAway®) was used.

Quality Control testing demonstrated acceptable results for Tigecycline.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SIEMENS HEALTHCARE DIAGNOSTICS, INC.
ELISABETH WARRINER
REGULATORY TECHNICAL SPECIALIST
1584 ENTERPRISE BLVD.
WEST SACRAMENTO CA 95691

November 8, 2013

Re: K131275
Trade/Device Name: MicroScan Dried Gram-Positive MIC/Combo Panels with Tigecycline (0.12 - 8mcg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: LTT, JWY, LRG, LTW
Dated: September 27, 2013
Received: September 30, 2013

Dear Ms. Warriner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131275

Device Name: MicroScan® Dried Gram-Positive MIC/Combo Panels with Tigecycline (0.12 – 8 mcg/ml)

Indications For Use:

The MicroScan® Dried Gram-Positive MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-positive bacteria. After inoculation, panels are incubated for 16 – 20 hours at 35°C +/- 1°C in a non-CO2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial **Tigecycline** at concentrations of 0.12 – 8 mcg/ml to the test panel. MicroScan® Dried Gram-Positive Tigecycline is a qualitative test.

Tigecycline has been shown to be active against the organisms listed below according to the FDA label for the antimicrobial.

Active *in vitro* and in clinical infections:
Enterococcus faecalis (vancomycin-susceptible isolates)
Staphylococcus aureus (methicillin-susceptible and -resistant isolates)

Active *in vitro* but clinical significance unknown:
Staphylococcus epidermidis (methicillin-susceptible and -resistant isolates)

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Ribhi Shawar -S
2013.11.07 08:12:19 -05'00'